

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 47-50, 52-54, 56, 58, and 59 are pending.

*Amendments to the Claims*

The claims have been amended to point out more particularly and claim more distinctly the invention. In particular, claim 53 has been amended to specify that the CEA agonist peptide is selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5, as supported by the specification at, for example, paragraphs 0013-0017 of U.S. Patent Application Publication 2004/0171796. Claim 53 also has been amended to recite that the immunostimulatory molecule is selected from the group consisting of interleukin 2, interleukin 6, interleukin 12, interferon gamma, tumor necrosis factor alpha, GM-CSF, B7.1, B7.2, ICAM-1, LFA-3, CD72, and cyclophosphamide, as supported by the specification at, for example, paragraph 0040 of U.S. Patent Application Publication 2004/0171796. No new matter has been added by way of these amendments.

*Summary of the Office Action*

The Office rejects claims 52, 58, and 59 under 35 U.S.C. § 112, first paragraph, for allegedly containing new matter.

The Office rejects claim 53 under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description and enablement.

The Office rejects claims 52, 58, and 59 under 35 U.S.C. § 102(b) as allegedly anticipated by WO 00/34494. The Office rejects claims 52, 58, and 59 under 35 U.S.C. § 102(e) as allegedly anticipated by (i) U.S. Patent Application Publication No. 2004/0019195 or (ii) U.S. Patent 6,969,609.

The Office rejects claims 47-49, 58, and 59 on the grounds of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 10, 18, 19, 26, and 27 of U.S. Patent 7,211,432 ("the '432 patent"). The Office also rejects claims 50, 52, 54,

and 56 on the grounds of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 10, 18, 19, 26, and 27 of the '432 patent, U.S. Patent 6,319,496, and WO 91/02805.

Reconsideration of these rejections is hereby requested.

*Discussion of New Matter Rejection*

The Office contends that claims 52, 58, and 59 contain subject matter that was not described in the specification at the time the application was filed. Applicants traverse this rejection for the following reasons.

One of ordinary skill in the art, upon reading the specification, would understand that the kits and compositions described therein could contain a nucleic acid molecule encoding an agonist peptide, as well as a vector comprising the nucleic acid molecule. In particular, the specification describes kits and compositions comprising the agonist peptide at, for example, paragraphs 0020-0023 of U.S. Patent Application Publication 2004/0171796. The specification also describes nucleic acids encoding the agonist peptide, as well as vectors comprising the nucleic acid, at, for example, paragraphs 0065-0073. Accordingly, based on the description in the specification, one of ordinary skill in the art would have understood that the agonist peptide in the kits and compositions could be encoded by a nucleic acid or expressed by a vector comprising the nucleic acid encoding the agonist peptide.

For these reasons, the subject matter of claims 52, 58, and 59 was described in the originally filed specification. Accordingly, the new matter rejection of claims 52, 58, and 59 is improper and should be withdrawn.

*Discussion of the Written Description and Enablement Rejections*

The Office contends that claim 53 lacks written description and enablement. In particular, the Office contends that the specification does not adequately describe or enable a kit comprising any CEA agonist peptide and a vector comprising a gene encoding CEA or a recombinantly produced CEA protein and any immunostimulatory molecule.

Claim 53, as amended, recites that the CEA agonist peptide is selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, and SEQ ID NO: 5, and the immunostimulatory molecule is selected from the group consisting of interleukin 2, interleukin 6, interleukin 12, interferon gamma, tumor necrosis factor alpha, GM-CSF, B7.1, B7.2, ICAM-1, LFA-3, CD72, and cyclophosphamide. The specification describes the CEA agonist peptides and immunostimulatory molecules at, for example, paragraphs 0013-0017 and 0040 of U.S. Patent Application Publication 2004/0171796.

The specification also describes a vector comprising a gene encoding CEA. In particular, the specification describes CTL responses to CEA observed in patients immunized with a recombinant vaccinia viral vector that expresses CEA (rV-CEA) at, for example, paragraphs 0004 and 0072 of U.S. Patent Application Publication 2004/0171796.

For the above-described reasons, the subject matter of claim 53 must be considered to be adequately described and enabled by the specification. Therefore, Applicants request that the written description and enablement rejections be withdrawn.

#### *Discussion of the Anticipation Rejections*

As discussed above in connection with the new matter rejection, claims 52, 58, and 59 are fully supported by the present application. Since the disclosure of the present application in that respect is the same as the disclosure of the earliest priority application, claims 52, 58, and 59 are entitled to an effective filing date corresponding to the filing date of the earliest priority application. As a result, the cited references are not prior art to claims 52, 58, and 59, and the anticipation rejection is improper and should be withdrawn.

#### *Discussion of the Obviousness-type Double Patenting Rejections*

Applicants will consider the filing of a terminal disclaimer over U.S. Patent 7,211,432 upon an indication of allowable subject matter in the present application.

*Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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